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# **CDC Health Advisory**

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## **False-positive Results with a Commercially-Available West Nile Virus IgM ELISA Kit**

### **Current Investigation**

The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and state health departments are investigating an increase in false-positive test results obtained with a commercially-available West Nile virus immunoglobulin M capture enzyme-linked immunosorbent assay (WNV IgM capture ELISA). On October 8, 2008, Inverness Medical (Princeton, NJ), the manufacturer of the implicated assays, voluntarily recalled two lots of their PanBio WNV IgM capture ELISA kit. One lot (#07262) was only distributed in Canada. The other lot (#08118) was distributed from July-September 2008 to four laboratories in the United States. The laboratories that used the recalled test kit include ViroMed (Minnetonka, MN), Meritcare Health System (Fargo, ND), Pennsylvania Department of Health (Exton, PA), and Baylor University Medical Center (Dallas, TX). Based on the investigation to date, this increase in false-positive results appears to be limited to these two lots of the PanBio kit. CDC and FDA will continue to monitor and evaluate any additional reports of false-positive tests that may have resulted from previous lots.

### **Background Information about WNV testing**

As background, there are four FDA-cleared WNV IgM ELISA kits from different manufacturers commercially-available in the U.S. According to the package inserts, all of these kits are indicated for use on serum to aid in the *presumptive* laboratory diagnosis of WNV infection in patients with clinical symptoms of meningitis or encephalitis. The package inserts also state that all positive results obtained with any of the commercially-available WNV test kits should be confirmed by additional testing at a state health department laboratory or CDC. Public health practitioners, healthcare providers and clinical laboratories are reminded to consider the intended use and limitations of these kits when requesting WNV testing and interpreting the results.

The testing laboratories specified above will work with CDC and state and local health departments to notify hospitals or healthcare providers who submitted specimens that tested positive between July and September 2008 using the recalled PanBio kit. If the original specimen is still available, it will be retested at a state public health laboratory or CDC using a different WNV IgM assay. Healthcare providers will be notified of the results. If the original specimen is not available, health departments will work with healthcare providers to decide if a new serum specimen should be obtained for WNV testing. As the investigation proceeds, the provisional number of WNV disease cases reported to CDC for 2008 will be adjusted, with information available at [www.cdc.gov/westnile](http://www.cdc.gov/westnile).

### **Recommendations**

False-positive test results that occurred between July and September 2008 may have led to an incorrect diagnosis in some patients. If the patient is still experiencing symptoms, additional evaluation and alternative diagnoses should be considered. State health departments can help healthcare providers decide if a new serum specimen should be obtained to test for WNV or another etiology.

### **Additional Information**

- For more information about false-positive WNV tests, refer to:  
[http://www.cdc.gov/ncidod/dvbid/westnile/wnv\\_DiagnosticsUpdate.html](http://www.cdc.gov/ncidod/dvbid/westnile/wnv_DiagnosticsUpdate.html).

- For more information on individual specimens affected by this commercial test recall, please contact the healthcare facility or reference laboratory that performed the WNV tests in question.

## DHEC Contact Information for Reportable Diseases and Reporting Requirements

Reporting of West Nile neuroinvasive disease is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2004 List of Reportable Conditions available at:

[http://www.scdhec.gov/health/disease/docs/reportable\\_conditions.pdf](http://www.scdhec.gov/health/disease/docs/reportable_conditions.pdf)

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

### Regional Public Health Offices – 2008

Mail or call reports to the Epidemiology Office in each Public Health Region.

#### Region 1

**Anderson, Oconee**  
220 McGee Road  
Anderson, SC 29625  
Phone: (864) 260-4358  
Fax: (864) 260-5623  
Nights / Weekends: 1-866-298-4442

#### Abbeville, Edgefield, Greenwood, Laurens, McCormick, Saluda

1736 S. Main Street  
Greenwood, SC 29646  
Phone: 1-888-218-5475  
Fax: (864) 942-3690  
Nights / Weekends: 1-800-420-1915

#### Region 2

**Greenville, Pickens**  
PO Box 2507  
200 University Ridge  
Greenville, SC 29602-2507  
Phone: (864) 282-4139  
Fax: (864) 282-4373  
Nights / Weekends: 1-800-993-1186

#### Cherokee, Spartanburg, Union

PO Box 4217  
151 E. Wood Street  
Spartanburg, SC 29305-4217  
Phone: (864) 596-2227, x- 210  
Fax: (864) 596-3443  
Nights / Weekends: 1-800-993-1186

#### Region 3

**Chester, Lancaster, York**  
PO Box 817  
1833 Pageland Highway  
Lancaster, SC 29721  
Phone: (803) 286-9948  
Fax: (803) 286-5418  
Nights / Weekends: 1-866-867-3886

#### Region 3 (continued)

**Fairfield, Lexington, Newberry, Richland**  
2000 Hampton Street  
Columbia, SC 29204  
Phone: (803) 576-2749  
Fax: (803) 576-2993  
Nights / Weekends: 1-888-554-9915

#### Region 4

**Clarendon, Kershaw, Lee, Sumter**  
PO Box 1628  
105 North Magnolia Street  
Sumter, SC 29150  
Phone: (803) 773-5511  
Fax: (803) 775-9941  
Nights/Weekends: 1-877-831-4647

#### Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion

145 E. Cheves Street  
Florence, SC 29506  
Phone: (843) 661-4830  
Fax: (843) 661-4859  
Nights / Weekends: (843) 660-8145

#### Region 5

**Bamberg, Calhoun, Orangeburg**  
PO Box 1126  
1550 Carolina Avenue  
Orangeburg, SC 29116  
Phone: (803) 533-7199  
Fax: (803) 533-7134  
Nights / Weekends: (803) 954-8513

#### Aiken, Allendale, Barnwell

1680 Richland Avenue, W. Suite 40  
Aiken, SC 29801  
Phone: (803) 642-1618  
Fax: (803) 643-8386  
Nights / Weekends: (803) 827-8668 or  
1-800-614-1519

#### Region 6

**Georgetown, Horry, Williamsburg**  
1931 Industrial Park Road  
Conway, SC 29526-5482  
Phone: (843) 915-8804  
Fax: (843) 365-0085  
Nights / Weekends: (843) 381-6710

#### Region 7

**Berkeley, Charleston, Dorchester**  
4050 Bridge View Drive, Suite 600  
N. Charleston, SC 29405  
Phone: (843) 953-0060  
Fax: (843) 953-0051  
Nights / Weekends: (843) 219-8470

#### Region 8

**Beaufort, Colleton, Hampton, Jasper**  
219 S. Lemacks Street  
Walterboro, SC 29488  
Phone: (843) 549-1516, x-214  
Fax: (843) 549-6845  
Nights / Weekends: 1-800-614-4698

#### DHEC Bureau of Disease Control Division of Acute Disease Epidemiology

1751 Calhoun Street  
Box 101106  
Columbia, SC 29211  
Phone: (803) 898-0861  
Fax: (803) 898-0897  
Nights / Weekends: 1-888-847-0902



[www.scdhec.gov](http://www.scdhec.gov)

#### Categories of Health Alert messages:

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action.